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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/415,890	10/08/1999	BORJE S. ANDERSSON	UTXC:528--1	5425

7590 09/20/2004

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EXAMINER
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LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/415,890

### Applicant(s)

ANDERSSON, BORJE S.

### Examiner

Neil Levy

### Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 94-97, 99 and 106-150 is/are pending in the application.
- 4a) Of the above claim(s) 94-97, 106-115, 123-132, 138-140 and 144-149 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 97, 99, 116, 117, 119, 121, 122, 141 and 150 is/are rejected.
- 7) ☒ Claim(s) 118, 120, 121, 134-137, 143, 144 and 150 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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Receipt is acknowledged of Brief of 6/14/04.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Examiner finds issues require reconsideration upon updated review and search.

The after final amendment, canceling

Claim 98, has been entered.

Appellants arguments re 112 are persuasive, examiner had interpreted solvent to mean all the claimed components were in solution however, the term is presented as descriptive rather than as mechanistic. The rejection is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 94-96, 106-115, 123-132, 138-140 and 144-149 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the <sup>paper #</sup> 19.

Claims 97, 116 are rejected under 35 U.S.C. 102(b) as being anticipated by Stehle et al GB 145732.

See example 1 – DMA, or DMSO – P. 5, lines 14-16 – is mixed with a co-solvent, water (p.5, line 43-52) and solvent is then removed, by filtration, and when use ~~is~~ desired, reconstituted.

Claims 97, 99, 116, 117, 119 are rejected under 35 U.S.C. 102(e) as being anticipated by Janoff et al 6,406,713.

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Janoff dissolves polyene, hydrophobic antibiotic in a dipolar aprotic solvent, DMSO (col. 4, lines 48-54), the instant claim 99 (pimaricin at col. 9, line 38) and step (a) of claim 97; followed by mixing in a pharmaceutically acceptable aqueous secondary solvent of saline, PBS or glycine buffer (col. 4, lines 55, 56-58), the instant claim 97 (b), followed by evaporation of solvents (col. 4, lines 52, 53, 58), the instant claim 97 (c), evaporation clearly resulting in all or virtually all solvents, more than 50%, being removed. Finally, the solvent vehicle/drug is reconstituted (Instant claim 97 (d)) as stated as hydrated with aqueous solution (col. 4, lines 61-64). See col. 11, last paragraph and top of col. 12 – a DMSO/Lipid vehicle and drug, mixed with pharmaceutically acceptable aqueous secondary solvent – PBS- is then subjected to evaporation and filtered, removing all supernatant – thus, removing over 50% solvents, as claimed in 97(c). The pellet is then resuspended in aqueous solvent – this is claim 97 (a) – reconstituting solvent vehicle by addition of a pharmaceutically acceptable aqueous solvent, since the preparation is then less toxic than prior drug compositions. The instant claims 16 recites comprises; water, saline. These are shown at col. 4, line 55, as equivalents of the exemplified PBS. An aqueous lipid emulsion (claim 117) is seen as the DMPC : DMPG homogenized with buffer or saline (col. 11, lines 13-16), or with soy lipid (col. 8, last paragraph, top col. 9).

Claims 97, 99, 116, 117, 119, 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff et al 6406713 in view of Szoka, Jr. 5277914, Janoff provides the instant invention, but uses only DMSO, although solvents such as DMSO is envisioned (col. 4, lines 49-50). Szoka discloses such solvents to include the instantly

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claimed DMF (col. 4, line 50, col. 5, lines 8-13), also used with co-solvents and the Janoff/instant ~~antibiotics~~ antibiotics: amphotericin, primaricin (col. 3, bottom).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to prepare stable hydrophobic antibiotic solvent vehicles, to prepare one of Janoff. The particular solvent is seen as one within the purview of the artisan to select, as equivalents taught by Szoka, Jr.

Appellant's arguments and have been considered and examiner agrees the particular combination lacks sufficient basis for prima facie obviousness. However, we find upon review, that the concept of the instant invention as it is claimed is evident in the prior art.

Claim 141 and 142, however are seen as claiming the instant concept.

Claims 97, 99, 116, 117, 119, 121, 122, 141, 150 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 27, 28, 30-32, 34 of copending Application No. 10/294,491. Although the conflicting claims are not identical, they are not patentably distinct from each other because the applications recite the same preparation steps, except for quantification and the obvious use step of reconstitution.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

<sup>97</sup>  
Claims ~~99~~ 99, 116, 119, 121, 122, 133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45-~~63~~ 63 are of copending Application No. 10/439,252. Although the conflicting

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claims are not identical, they are not patentably distinct from each other because the applications recite the same process steps, inclusive of the ingredients of dependent claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 118, 120, 134-137, 142, 143 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NEIL S. LEVY  
PRIMARY EXAMINER